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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,781	04/21/2004	Donna E. Fennell	RU-0224	5233
7590 Jane Massey Licata Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053				
			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 04/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/828,781

**Applicant(s)**

FENNELL ET AL.

**Examiner**

Irene Marx

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/09 has been entered.

The Ward and Cupples references filed 3/12/09 have been considered only to the extent argued. In the absence of a proper 1449 form, the documents will not be listed on any patent that matures from this application.

Claims 1-7 are being considered on the merits.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adrian *et al.* taken with Maymo-Gatell *et al.* in light of Bunge *et al.*

Adrian *et al.* teach a process of dehalogenation of aromatic chlorinated compounds with the strain *Dehalococcoides* CBDB1. See, e.g., Col. 2, paragraph 1. It is noted that Adrian *et al.* uses a mixed culture and provides an electron donor, such as hydrogen (page 581, paragraph 1.)

The references differ from the claimed invention in that the strain cultured does not appear to be strain *Dehalococcoides ethenogenes* 195. However, the strain cultured is very closely related to this strain as shown in Fig. 2 of Adrian *et al.*

Moreover, Bunge *et al.* adequately demonstrates that the strain taught therein has 16S ribosomal DNA having 98.5% identity with strain *Dehalococcoides ethenogenes* 195 (See, e.g., page 358, paragraph 2).

Strain *Dehalococcoides ethenogenes* 195 is known in the art to be capable of the dehalogenation of aliphatic compounds, such as tetrachloroethene, as adequately demonstrated by Maymo-Gatell *et al.* and uses hydrogen, butyrate or methanol as electron donors (page 1569, paragraph 2). One of ordinary skill in the art would have been motivated to add a simple halogenated compound to the bioconversion medium of strain *Dehalococcoides ethenogenes* 195, given that this strain, for example, was known to grow well on tetrachloroethene and hydrogen at the time the claimed invention was made. See, e.g., Maymo-Gatell *et al.*, page 1570, col. 2, paragraph 2).

One of ordinary skill in the art would have had a reasonable expectation of success in process of dehalogenating aromatic compounds with strain *Dehalococcoides ethenogenes* 195 in view of the teachings of Adrian *et al.*, in light of Bunge *et al.*, of a very closely related strain *Dehalococcoides* CBDB1 that is capable of this bioconversion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Adrian *et al.* by replacing strain *Dehalococcoides* CBDB1 with strain *Dehalococcoides ethenogenes* 195 in view of their close relatedness and the teachings of Maymo-Gatell *et al.* regarding the dehalogenating properties of strain 195 for the expected benefit of providing an effective process of bioremediation for very toxic and health-damaging environmental pollutants, such as dioxins.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding the differences between *Dehalococcoides* CBDB1 and *Dehalococcoides ethenogenes* are duly noted. However, applicant fails to consider that the Adrian *et al.* reference suggests that *Dehalococcoides ethenogenes* 195 and *Dehalococcoides* CBDB1 have similar dechlorinating capabilities as suggested by the finding that in both of these strains reductive dehalogenation of chlorinated compounds is the only energy conserving process found. Moreover that the strains are closely related as they belong to the same genus is shown in Figure 2. Therefore, even though the strains do not appear to be identical one of ordinary skill in the art would have recognized their similarity and would thus have reasonably expected at the time the claimed invention was made that *Dehalococcoides ethenogenes* 195 would be suitable to perform similar dehalogenation reactions on aromatic halogenated compounds as strain *Dehalococcoides* CBDB1 See, also Figure 3 in Bunge *et al.*

It is emphasized that this obviousness rejection is based on the close relatedness between the reference and claimed strain, which both belong to the same genus *Dehalococcoides*. Applicant cites Ward for broad teachings regarding metabolic differences between organisms as well as the lack of absolute predictability of 16S rRNA sequences regarding metabolic capabilities between strains. These broad teachings are not relevant to the invention as claimed with any specificity. Applicant also cites the abstract of Cupples (2008) as showing that strains with the same 16S RNA gene sequence can have different dehalogenating abilities. Whether this is applicable to the two strains of interest is not particularly shown. In addition, this information was not available to one of ordinary skill in the art at the time the claimed invention was made.

Even though the strains *Dehalococcoides ethenogenes* 195 and *Dehalococcoides* CBDB1 are not the same and have certain differences in metabolic requirements, they belong to the same genus *Dehalococcoides* and would have been reasonably expected to successfully perform a process of removing at least one halogen group from a halogenated aromatic compound, as in claim 1, at the time the claimed invention was made, due to the teachings of the references. Applicant has not demonstrated differences or unexpected results in the claimed process between the claimed strain and the reference strain, which both appear to belong to the genus *Dehalococcoides* and which are both known to successfully decompose halogen containing compounds.

That the two strains of interest are closely related cannot be denied, even if the similarity between the 16S rRNA is not absolutely predictive of the functional genes an organism may possess. Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.). See, MPEP 2143.02.

In addition, it is noted that claims 5 and 7 do not require the use of strain *Dehalococcoides ethenogenes* 195. Therefore the arguments do not pertain to these claims.

Therefore the rejection is deemed proper and it is adhered to.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
Art Unit 1651